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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09 626,127 | 07 26 2000 | Robert L. Erwin | 00801.0087.CPUS04 | 7695 |

7590

09/12 2003

Tom Gallegos, Sr. Director, Intellectual Property
Large Scale Biology Corporation
3333 Vaca Valley Parkway
Suite 1000
Vacaville, CA 95688

EXAMINER

RILEY, JEZIA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

34

DATE MAILED: 09 12 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/626,127

Applicant(s)

GARGER ET AL.

Examiner

Jezia Riley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 64-90 is/are pending in the application.
- 4a) Of the above claim(s) 85-88 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 90 is/are allowed.
- 6) ☒ Claim(s) 2, 64, 67, 68, 71-78, 80-82 and 89 is/are rejected.
- 7) ☒ Claim(s) 65, 66, 69, 70, 79, 83 and 84 is/are objected to.
- 8) ☒ Claim(s) 2 and 64-90 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement (PTO-1413) (Page No. _____)
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other _____

DETAILED ACTION

Response to Remarks

1. Applicants' arguments and amendments, filed on 7/14/03, have been approved and entered. They have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

2. Newly submitted claims ~~85-88~~⁸⁵⁻⁸⁷ are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 71-90 are directed to methods, plants, seeds, cells, leaf, etc. which are different inventions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 85-87 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. This application contains claims 85-88 drawn to an invention nonelected. A

then appropriate action is 37 CFR 1.144. See MPEP § 821.1.

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Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 2, 64, 67, 68, 71-78, 80-82, 89 are rejected under 35 U.S.C. 102(e) as being anticipated by Desnick et al. (5,580,757).

Desnick et al discloses the production of biologically active human alpha-Galactosidase (.alpha.-Gal A) involving cloning and expression of the genetic coding sequence for alpha-Gal A in eukaryotic expression systems which provide for proper post-translational modifications and processing of the expression product.

The invention involves the production of large quantities of human alpha-Gal A by

expression systems. In cases where plant expression vectors are used, the expression

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of the .alpha.-Gal A coding sequence may be driven by any of a number of promoters. For example, viral promoters such as the 35S RNA and 19S RNA promoters of CaMV, or the coat protein promoter of TMV may be used; alternatively, plant promoters such as the small subunit of RUBISCO or heat shock promoters, e.g., soybean hsp17.5-E or hsp17.3-B may be used. These constructs can be introduced into plant cells using Ti plasmids, Ri plasmids, plant virus vectors; direct DNA transformation; microinjection, electroporation, etc. (col. 16).

Alternative eukaryotic expression systems which may be used to express the .alpha.-Gal A enzymes are yeast transformed with recombinant yeast expression vectors containing the .alpha.-Gal A coding sequence; insect cell systems infected with recombinant virus expression vectors (e.g., baculovirus) containing the .alpha.-Gal A coding sequence; or plant cell systems infected with recombinant virus expression vectors (e.g., cauliflower mosaic virus, CaMV; tobacco mosaic virus, TMV) or transformed with recombinant plasmid expression vectors (e.g., Ti plasmid) containing the .alpha.-Gal A coding sequence.

Alpha.-Gal A is a galactosyl hydrolase which has activity toward various oligosaccharides, glycoproteins, glycopeptides and glycolipids with terminal .alpha.-galactosidic linkages. Thus, the enzyme can be used in vitro to modify these .alpha.-galactoglycoconjugates. For example, the recombinant .alpha.-Gal A of the invention could be utilized for a variety of desirable modifications including but not limited to: (a) antigen, and (b) the hydrolysis of stachyose to raffinose, raffinose to the disaccharide

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sucrose, or the hydrolysis of melibiose to galactose and glucose. Such hydrolyses have commercial applications as in the degradation of molasses as a substrate for yeast production. (section 5.3.2).

7. Claims 65, 66, 69, 70, 79, 83, 84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claim 90 is allowed.

9. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855.

The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's


organization where this application is proceeding is assigned to the examiner.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


JEZIA RILEY
PRIMARY EXAMINER